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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,082	02/09/2005	Keith Alan Charlton	133088.00201(P35262US)	8653

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EXAMINER	
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ART UNIT	PAPER NUMBER
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/524,082	CHARLTON ET AL.	
	Examiner	Art Unit	
	Mark Navarro	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 August 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11,12 and 33-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11,12 and 33-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/15/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants amendment filed August 19, 2009 has been received and entered. Claims 1-10, 13-32 have been cancelled and new claims 34-41 have been added. Accordingly, claims 11-12 and 33-41 are pending in the instant application.

Claim Rejections - 35 USC § 102

1. The rejection of claims 19-20, 24-29 and 32 are rejected under 35 U.S.C. 102(e) as being anticipated by Kende et al is withdrawn in view of the cancellation of said claims.

Claim Rejections - 35 USC § 103

2. The rejection of claims 1-2, 6-12, 17-20, 24-29, and 32 under 35 U.S.C. 103(a) as being unpatentable over Kende et al in view of McCafferty et al is withdrawn in view of Applicants amendment.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163

USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. The provisional rejection of claims 11-12 and 33-41 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the claims of copending Application No. 10/599,355 is maintained. Although the conflicting claims are not identical, they are not patentably distinct from each other because each set of claims encompasses methods of using monoclonal antibodies to a homoserine lactone molecule of Formula I.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicants are asserting that should provisional obviousness-type double patenting rejections be the only remaining rejections remaining in the present application, the rejection should be withdrawn as set forth in MPEP 804. Applicants assertions are correct, however, the provisional obviousness-type double patenting rejection is not the sole remaining rejection at present. Accordingly, this rejection is maintained for reasons of record.

4. The provisional rejection of claims 11-12 and 33-41 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the claims

of copending Application No. 11/568,673 is maintained. Although the conflicting claims are not identical, they are not patentably distinct from each other because each set of claims encompasses methods of using monoclonal antibodies to a homoserine lactone molecule of Formula I.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicants are asserting that should provisional obviousness-type double patenting rejections be the only remaining rejections remaining in the present application, the rejection should be withdrawn as set forth in MPEP 804. Applicants assertions are correct, however, the provisional obviousness-type double patenting rejection is not the sole remaining rejection at present. Accordingly, this rejection is maintained for reasons of record.

The following new grounds of rejection are applied in view of Applicants amendment:

Claim Rejections - 35 USC § 112

5. Claims 34-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claims 34-40 recite monoclonal antibodies identified "according to the method of

claim 11."

The specification and claims do not indicate what distinguishing attributes are shared by the members of the genus. Thus, the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, "identified by the method of claim 11" alone is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus.

Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The protein itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed."

Applicant is reminded that Vas-Cath make clear that the written description provision of 35 USC 112 is severable from its enablement provision.

Applicants are directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement, the guidelines can be found at the following link on the USPTO Internet in "Patents Guidance" Specifically, Example 17, which is analogous to the recitation of a claimed product identified via a method of production.

<http://www.uspto.gov/web/patents/guides.htm>

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 34-40 are rejected under 35 U.S.C. 102(e) as being anticipated by Kende et al.

The claims are drawn to a monoclonal antibody identified according to the method of claim 11 (e.g.,to a molecule of a homoserine lactone of Formula I, specifically N-butanoly-L-homoserine lactone).

Kende et al (US Patent Number 6,713,059) disclose of monoclonal antibodies to N-butanoly-L-homoserine lactone. (See claim 4). Kende et al further disclose of

methods of treating or preventing an infectious disease comprising administering the antibody to a subject. (See paragraph 23). Kende et al futher disclose of single chain antibodies. (See paragraph 39).

Claims 34-40 all claim a monoclonal antibody based on its method of production (e.g., selected from a human antibody phage display library). "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Given that Kende et al disclose of monoclonal antibodies which specifically bind N-butanoly-L-homoserine lactone, the teachings of Kende et al are deemed to anticipate the presently claimed monoclonal antibodies which also bind N-butanoly-L-homoserine lactone, which were produced via the method of claim 11. Since the Patent office does not have the facilities for examining and comparing Applicants product with the product of the prior art reference, the burden is on Applicants to show an unobvious distinction between the material structural and functional characteristics of the claimed product and the product of the prior art. *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 11-12 and 34-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kende et al in view of McCafferty et al and Chang et al.

The claims are directed to a method of screening a naïve human phage display library for an anti-bacterial monoclonal antibody comprising conjugating a homoserine lactone molecule of Formula I to a first carrier molecule to generate an enriched library, and screening said enriched library against the homoserine lactone molecule conjugated to a second different carrier molecule to identify a monoclonal antibody that specifically binds to the free soluble form of the homoserine lactone or a C_1-C_{10}

saturated or unsaturated carboxylic acid derivative thereof from the enriched library in the presence of conjugated derivatives thereof.

The teachings of Kende et al are set forth above.

Kende et al do not teach of selecting a monoclonal antibody from a naive human antibody phage display library or of screening the homoserine lactone molecule conjugated to a second, different carrier molecule.

McCafferty et al (Nature Vol. 348, No. 6301, pp 552-554, Dec. 1990) teach that at the time of the instant application, it was routine to select monoclonal antibodies from a naïve human antibody phage display library. (See abstract).

Chang et al (US Patent Number 5,254,671) teach that at the time of the instant application, it was understood that "carrier molecules" often form epitopes that result in antibody binding both the intended target molecule as well as the carrier molecule. Chang et al further teach that it was routine in the art at the time of the invention to use a different carrier molecule to screen hybridomas for monoclonal antibodies, the process resulting in the selection of antibodies which are specific for the intended molecule of interest instead of cross reacting with the carrier protein which was used to elicit the antibody in the first place. (See Detailed specification paragraph 62).

Given that Kende et al have taught of monoclonal antibodies which bind a homoserine lactone molecule of Formula I, and that McCafferty et al have taught that it was routine in the art to select monoclonal antibodies from a naïve human antibody phage display library, and that Chang et al have taught of the advantages of using a second different carrier to screen hybridomas for monoclonal antibodies which result in

monoclonals which bind the intended target alone, it would have been prima facie obvious to have generated a monoclonal antibody which binds a homoserine lactone molecule of Formula I from a naïve human antibody phage display library as taught by McCafferty et al for use in the method as taught by Kende et al, it would have been further obvious to include a second different carrier protein as taught by Chang et al to screen the hybridomas for monoclonals which bind the intended antigen and do not cross react with the original carrier protein's neo epitopes.

The U.S. Supreme Court has very recently addressed the obviousness of a combination of known elements. A rigid application of the Court of Appeals for the Federal Circuit's "teaching, suggestion, or motivation" test was rejected, the Court stated that a "combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results. *KSR International Co. v. Teleflex Inc. et al.,* No. 04-1350, slip op. at 12 (S. Ct., April 30, 2007).

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on (571) 272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark Navarro/
Primary Examiner, Art Unit 1645
December 1, 2009